

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 23 DEC 2004

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| Applicant's or agent's file reference 27131 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/IL03/01011 | International filing date (day/month/year) 27 November 2003 (27.11.2003) | Priority date (day/month/year) 29 November 2002 (29.11.2002) |
| International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/02, 1/48, 1/34, 1/37; C12M 1/00; G01N 33/53 and US Cl.: 435/29, 7.1, 15, 18, 23, 24, 4, 283.1, 968 | | |
| Applicant MEISHAR H.Z. YAZAMUT LTD. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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| Date of submission of the demand 17 May 2004 (17.05.2004) | Date of completion of this report 12 November 2004 (12.11.2004) |
| Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | Authorized officer Louise N. Leary <i>J. Roberts for</i> Telephone No. (571)272-1600 |

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-75 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the claims:
pages 76-86 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the drawings:
pages 1-11 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 9-31, 40-64, and 78-82

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 9-31, 40-64 and 78-82

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

| | | |
|-------------------------------|---|-----|
| Novelty (N) | Claims <u>NONE</u> | YES |
| | Claims <u>1-8,32-39,65-77 and 83-86</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-8,32-39,65-77 and 83-86</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-8,32-39,65-77 and 83-86</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-8, 32-39, 65-77 and 83-86 lack novelty under PCT 33(2) as being anticipated by SEI-LIDA et al. SEI-LIDA et al disclose methods for monitoring protein synthesis in a protein synthesis system comprising a detectable marker. SEI-LIDA et al detect RNA synthesis in in vitro transcription reactions using FRET. SEI-LIDA et al also describes an apparatus for performing real-time methods. See the entire ABSTRACT ONLY.

Claims 1-8, 32-39, 65-77 and 83-86 lack an inventive step under PCT Article 33(3) as being obvious over SEI-LIDA et al. SEI-LIDA et al disclose methods for monitoring protein synthesis in a protein synthesis system comprising a detectable marker. SEI-LIDA et al detect RNA synthesis in in vitro transcription reactions using FRET. SEI-LIDA et al describe an apparatus for performing real-time tRNAs were also used in the methods. See entire ABSTRACT ONLY.

Claims 1-8, 32-39, 65-77 and 83-86 lack an inventive step under PCT 33(3) as being obvious over Rothchild et al (6,210,941 B1). Rothchild et al disclose methods for detection and isolation of proteins. Detectable marker labels were also used in the methods. tRNAs were also characterized. Note entire document.

Claims 1-8, 32-39, 65-77 and 83-86 lack an inventive step under PCT 33(3) as being obvious over Rothchild et al (5,922,858 A). Rothchild et al disclose methods for detecting and isolating proteins. Detectable marker labels were also used in the methods. tRNAs were characterized. See entire document.

Claims 1-8, 32-39, 65-77 and 83-86 meet the criteria set out in PCT Article 33(4), and thus the invention has industrial applicability because the subject matter claimed can be made or used in industry.